

REMARKS

Claims 1-16, 20-22, 26, 64, 65, and 67-80 are pending in the application, although claim 78 is cancelled herein. Claim 76 is amended herein without prejudice and without acquiescence to further the prosecution of this case. Applicants reserve the right to pursue original material upon subsequent prosecution.

Issues under 35 U.S.C. § 102(b)

Claim 76 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ersek et al. (U.S. Patent No. 5,258,028).

As presently amended, Claim 76 encompasses a shaped particle being shaped such that *each* of the interstitial spaces of one particle will accept only one extremity of an adjacent particle. Given the irregularity of the size and position of the extremities depicted in Ersek, more than one extremity would fit in an interstitial space in Ersek. For example, of the smaller triad of extremities on the front side of the particle in **Fig.-5**, the two extremities pointing northwest and northeast would fit into the single inter-pillar indentation of 43.

Therefore, all of the elements of Applicants' claim 76 are not taught by Ersek, and Applicants respectfully request removal of this rejection.

Issues under 35 U.S.C. § 103(a)

Claims 1-4, 9-11, 14-16, 20-22, 26, 64, 65, 69, 70, and 73-80 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,178,201 ("Ahlers") in combination with Black (U.S Patent No. 5,676,700); Black and Chen (U.S. Patent No. 6,180,606); and Black and Barralet (Biomaterials, 1993). Applicants respectfully disagree.

A. All Limitations Are Not Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). By the Examiner's own admission ("... Ahlers fails to disclose the extremities as being tapered..."; Page 3 of the Action), Ahlers lacks the teaching of the tapered extremities, and it also does not suggest tapering of the extremities. There is no

indication from Ahlers that tapering of the arms of the particles bonded to the implant would be useful or required. Therefore, there is no teaching, suggestion, or motivation to combine the content of the references to achieve Applicants' invention. By definition there is no *prima facie* obviousness of the claimed invention. Furthermore, Ahlers not only does not teach or suggest the materials mentioned in Black, such as ceramic or bioactive glass, or Chen, such as calcium compounds and polymers, but Ahlers teaches materials wholly unsuitable for bone grafting (see above discussion), so there can be no suggestion or motivation concerning these elements either.

There must be a teaching or suggestion to make the claimed limitations, and Applicants remind the Examiner that the level of skill in the art cannot be relied upon for suggestion. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Thus, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. §103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

Obviousness can not be based on "common knowledge and common sense of a person of ordinary skill in the art *without any specific hint or suggestion in a particular reference.*" *In re Lee* 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). As such, all claim elements are not suggested in the combination of the references.

B. Ahlers and Combinations Therewith Teach Away from the Claimed Invention

Applicants strongly assert that Ahlers as a whole teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Applicants invention is not obvious in light of Ahlers in combination with any of the cited references, because Ahlers itself teaches away from the present invention. First and foremost, the field of use for Ahlers' invention and the field of use of Applicants invention are entirely different. Ahlers teaches implants, whereas Applicants provide for bone graft

substitutes, and although they very generally both regard bone, their specific use and purpose are not within the same discipline.

For example, Ahlers provides for means of an implant structure to obtain a large surface area for the purpose of avoiding juxtaposition of a flat metal piece of implant against bone. Ahlers places the part of the implant shaped similarly to our invention upon the surface of the implant to facilitate implant fixation and to ensure that the bone affixes to the implant, thereby preventing mobility of the implant. The purpose of Ahlers is not to repair bone but to provide for a means to juxtapose a permanent implant next to bone. Ahlers concerns providing implants utilizing "surface structures of the implant...[that] are discrete and so stable, that an additional treatment of the positive pattern is not necessary..." (col. 2, lines 30-32). Ahlers teaches the particles having three pins bonded to the basic pattern (at least at col. 3, lines 3-4) and as an entire structural entity being the particles bonded to the implant backbone, this would be utilized for the duration of the lifetime of the individual. While the shape of the particles which are bonded to the implant may be similar, Ahlers does not teach that this shape would be suitable for repairing bone to its natural state, which is the purpose of a bone graft substitute such as Applicants' invention, and it is not obvious that the Ahlers' implant particles would be beneficial for such a purpose.

The design of Ahlers' implant teaches away from the design of Applicants' invention. Whereas the design of Applicants' invention provides for restoration of bone tissue and bone ingrowth, the design of Ahlers' invention, comprising as a whole the particles bonded to an implant, provides for a solid outer surface of an implant to provide a means to attach to a nearby bone. Applicants' invention utilizes the particles as loose granules for a temporarily scaffold, in contrast to Ahlers' fixed immobile bipartite structure comprised of these particles bonded to the implant. Therefore, one would not consider this relevant in the field of bone graft substitutes in which it is useful to have a temporary scaffold in a defect that goes away with time. Given that the bonded particles would be insufficient for the purpose of providing temporary scaffolding to fill a bone defect, a skilled artisan would not consider Applicants' invention obvious, particularly when the bonded fixed particle structure is wholly unsuitable to fill an irregularly shaped bone defect.

In particular regard to claims 4-13, 64,65 and 68, and in addition to the structure of Ahlers' bonded particle implant teaching away from Applicants' invention, the materials taught by Ahlers also teach away because they are unsuitable and would not render Applicants' invention obvious. Ahlers does not teach using resorbable materials to replace missing bone with healthy bone, because this is not the purpose or field of his invention. Ahlers teaches utilizing materials that are not resorbable, such as wax, polypropylene, polyethylene, or PMMA, all of which are inappropriate for use in a bone graft substitute. In fact, a skilled artisan would not recognize Applicants' invention as obvious when Ahlers teaches materials that would not only fail to recruit bone cells, such as for Applicants' field of use in bone graft substitutes, but the materials are not known to be osteoconductive. Bone cells are not attracted to these materials, so bone would not be laid down surrounding them. The utilization of materials in bone graft substitutes that are not conducive to laying down bone is contrary to accepted wisdom in the art, which is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).

The objective in optimizing shapes of bone graft substitute particles, such as with Applicants' invention, is to repair bone to its original state where there is a void of bone. This would require biocompatible, resorbable materials that attract osteoblasts or osteoblast-like cells such that these cells will lay down bone and continue to lay down new bone as the bone graft material resorbs. Not only is this not taught or suggested in Ahlers, but Ahlers' invention teaches away from Applicants' invention by the nature of implant use. For example, for utilizing an implant such as Ahlers' implant, a medical provider must remove bone, thereby cutting a defect in the bone upon implantation of the implant. As a result, the defect in the bone will never heal. In an opposite manner, Applicants' invention facilitates healing of an existing defect through resorption of the shaped bone graft substitutes and recruitment of bone cells. These are conflicting fields of use, and a skilled artisan would not make the connection between Ahlers' bonded particle-implant structure to Applicants' moveable bone graft substitute configuration.

In summary, Ahlers' structure teaches away from Applicants' structure, because the fixed immobile particles are bonded to an implant and are wholly unsuitable for filling a bone defect, and Ahlers' materials teach away from Applicants' materials because they are both non-resorbable and incapable of attracting bone cell growth. Thus, Applicants assert that Ahlers teaches away from the present invention, indicating that the pending claims are,

in fact, not obvious.

Given that Ahlers itself teaches away from the present invention and does not render Applicant's invention obvious, then the combination of references with Ahlers also teach away from the invention.

Therefore, it is not obvious to utilize Ahlers' invention in combination with Black's teaching to develop a bone graft substitute, and certainly not in combination with Chen or Barralet when the fundamental nature of Ahlers invention is unsuitable for Applicants' bone graft substitutes. One skilled in the art in the development of a bone graft substitute would not utilize ideas from implant fixation techniques separately or in combination with bone repair or augmentation patents.

C. The Proposed Modification Cannot Render the Prior Art Unsatisfactory for its Intended Purpose

If a proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the particles of Black, being separate entities that are not bonded to themselves or another structure, were used with an implant, the advantage of Ahlers' modified surface structure would be obsolete, given that the particles would not be affixed to the implant. Furthermore, if the calcium materials of Chen were utilized in the particles bonded to Ahlers implant, the particles would likely resorb and render the implant unstable, which would certainly be unsatisfactory for a permanent implant. Therefore, the combination of Ahlers with Black, Black and Chen, and Black and Barralet are improper because Ahlers' implant structure would be unsatisfactory upon modification in accordance with these combinations.

The proposed modification or combination of the prior art can not change the principle of operation of the prior art invention being modified, or else the teachings are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Such modifications would also change the principle of operation of

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Ahlers' implant, given that the modified structures would no longer function suitably as an implant.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01952US0 from which the undersigned is authorized to draw.

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Respectfully submitted,

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